



# NELFINAVIR (NFV)

## GENERAL INFORMATION

- Therapeutic class: Protease inhibitor (PI).
- WHO Model List of Essential Medicines (EML): Not included in the 17th edition.<sup>24</sup>
- Patents: The basic patent was applied for in 1994 by Agouron Pharmaceuticals Inc.,<sup>207</sup> and is due to expire in 2014. Agouron Pharmaceuticals is now a subsidiary of Pfizer. NFV was developed by Agouron as part of a joint venture with Japan Tobacco, Inc. NFV is supplied by Roche outside the U.S., Canada and Japan.<sup>208</sup>
- WHO guidelines: Not currently included in WHO guidelines.
- World sales of originator product: 2004: US\$ 259 million. After 2004, there are no sales figures listed in the company's annual report.<sup>206</sup>
- Originator company and product brand name: Roche, Viracept.
- First approval by U.S. Food and Drug Administration (FDA): March 1997.<sup>23</sup>

## PRICE INFORMATION

### Developing country prices in US\$ per patient per year, as quoted by companies.

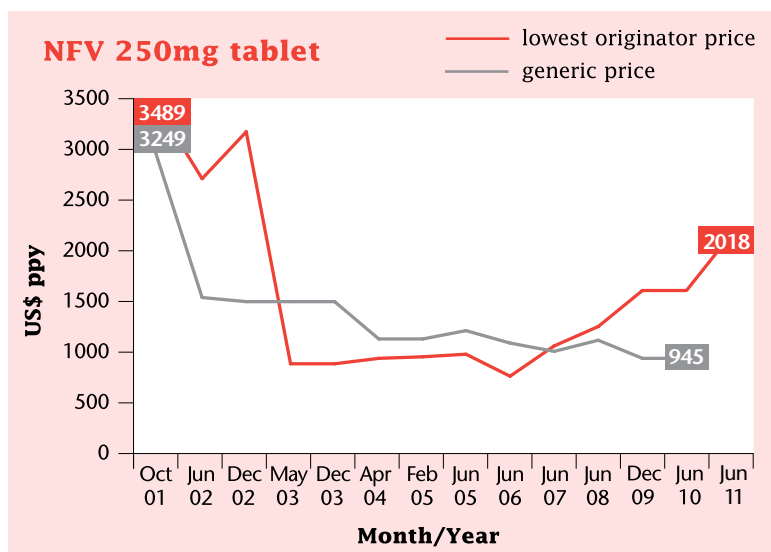
The price in brackets corresponds to the price of one tablet / gram of oral powder. Products quality-assured by US FDA or WHO prequalification (as of May 2011) are in **bold**.

	Daily dose	Roche	
		Category 1 countries	Category 2 countries
Who can access this price?		See annex 2	
NFV 50mg/g oral powder	24g	<b>2742</b> <b>(0.313/g)</b>	<b>3171</b> <b>(0.362/g)</b>
NFV 250mg tablet	10	<b>2018</b> <b>(0.553)</b>	<b>3132</b> <b>(0.858)</b>

### Evolution of the lowest quoted price for developing countries since 2001:

For the first time since 2001, no generic companies provided prices this year for nelfinavir 250mg tablet for this publication.

After a sharp decrease of the price of the originator between 2002 and 2003, this price has then steadily increased every year since 2006, by a total of 166%.



## SPOTLIGHT ON ACCESS ISSUES

Nelfinavir (NFV) is the only protease inhibitor (PI) that does not require boosting with ritonavir (RTV).

The large pill burden (10 tablets a day for an adult) and its high price make it a less-desirable option when selecting a PI.

In June 2007, Roche recalled all batches of NFV due to high levels of Ethyl Methane Sulphonate (EMS), a by-product of the manufacturing process and a known carcinogen in animals. Roche's marketing licence for NFV was suspended in Europe and WHO Prequalification temporarily suspended the product. In September 2007, the suspensions were lifted and marketing licences reinstated.<sup>209</sup> As a result of the recall, many patients were changed to

another PI. The recall highlights the risks associated with relying on a single producer for a medicine.

It is unknown if there will continue to be demand for the NFV formulation in the future. NFV was also deleted from the 16th edition of the WHO Model List of Essential Medicines (EML).

### Patents

Although basic patents on NFV could not be applied for in India because the country did not grant patents on pharmaceuticals at the time, Agouron applied for patents in many other developing countries. This factor contributes to the high price of the drug, together with the small demand.

### Paediatrics

In 1997, NFV was approved for use in children.<sup>210</sup>

The use of NFV oral powder in children is extremely complex. To obtain the correct dose for a 10kg child, 12g of the oral powder must be mixed with water. Access to clean, safe water is often not assured in all developing countries.

Not only is the paediatric NFV formulation ill-adapted, but its price remains prohibitive.